

U.S.S.N. 10/713,472  
Filed: November 14, 2003  
RESPONSE TO NOTICE OF  
NON-COMPLIANT AMENDMENT

### REMARKS

#### Drawings

The specification has been amended to delete the reference to photographs, and the photographs of Figures 2-5, due to the difficulty and expense of including photographs, and because they are not essential to an understanding of the claimed invention. The text from the brief description of the figures has been inserted in place of the reference to the figures, as appropriate.

The reference numbers shown in Figure 1 are described in the application as originally filed. The examiner's attention is drawn to page 28, lines 20-32.

#### Claim Numbering

The newly added claims have been renumbered as appropriate in view of the earlier cancelled claims 45-53.

#### Title

The title has been amended to refer to a "Population of Undifferentiated Neuroendocrine Cells".

#### Priority

The priority claim has been amended to delete the reference to U.S.S.N. 09/066,038 filed April 24, 1998, now U.S. Patent No. 6,027,774. This patent describes hydrogel-support structures for implantation of cells. It does not describe isolating undifferentiated neuroendocrine stem cell populations.

#### New Claims

Support for new claims 55 and 56 can be found at page 52, lines 15-18. Support for new claim 57 is found at page 52, lines 2-4. Support for new claims 58 and 59 is found at page 12,

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lines 1-17, and page 14, lines 29-30. Support for new claim 60 is found at page 14, lines 8-10; support for new claim 61 is found at page 14, lines 15-22.

Rejections under 35 U.S.C. 112

Claim 54 was rejected as indefinite under 35 U.S.C. 112, since the rotor centrifugal force was not defined. This rejection is mooted by the amendment to claim 54 which provides that the cells are washed in buffer after digestion with trypsin, then the buffer separated from the cells by centrifugation. Support for this amendment is found on page 52, at lines 1-4.

Claims 43, 44, and 54 were rejected under 35 U.S.C. 112 as lacking written description and enablement. These rejections are respectfully traversed.

The written description defined by 35 U.S.C. 112 must be sufficient to convey to one of ordinary skill in the art that applicants have the claimed invention within their possession. This is clearly the case here where the examples demonstrate actual reduction to practice prior to the application being filed, of the isolation of stem cells from neuroendocrine tissue.

While the examiner has done an admirable job of detailing the history of the isolation of stem cells from pancreas as of the priority date of this application and beyond, this is irrelevant to an analysis of whether or not applicants have complied with 112 written description, which is done based on an analysis of the specification *per se*, not the prior art - indeed, what the examiner has done is argue the novelty and non-obviousness of what is claimed. There is a presumption that an application is enabling. The examiner must provide more than mere assertion that the claims are not enabled or in compliance with the written description requirement.

The applicants explain that the digestion of tissue with a weak trypsin solution and trituration is effective to kill differentiated cells, leaving undifferentiated cells (see, for example,

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page 6, lines 18-33; page 26, lines 15-25; page 27 lines 9-22; see especially page 44, lines 15-29). The examples demonstrate the isolation of neural as well as neuroendocrine undifferentiated cells, and implantation into structures where they proliferate and remain viable. The specification teaches not only how to obtain the cells but how to keep the cells in culture in an undifferentiated form.

Since this rejection may in fact be due to the use of the term "stem" cells, the claims have been amended to reference an "undifferentiated cell population" isolated from neuroendocrine tissue. Support can be found in the specification as noted above.

Rejection under 35 U.S.C. 102

Claims 43 and 44 were rejected under 35 U.S.C. 102(b) as disclosed by Cornelius, et al., Horm. Metab. Res. 29(6):271-277 (1997). This rejection is respectfully traversed if applied to the amended claims.

All claims now recite a population of undifferentiated cells obtained from dissociated neuroendocrine tissue digested with a trypsin like enzyme.

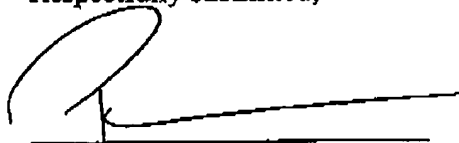
Cornelius does not disclose the claimed cell population.

In summary, the claims are drawn to definite, enabled, and novel subject matter. The specification demonstrates that the claimed subject matter was fully reduced to practice and described generally and as a working example in the specification as originally filed, in compliance with all requirements under 35 U.S.C. 112.

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Allowance of claims 43, 44 and 54-61 is respectfully solicited.

Respectfully submitted,

  
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